

Response to Office Action mailed May 21, 2007

Submitted November 20, 2007

Application No.: 10/019,740

Attorney Docket No.: INL-091

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LISTING OF THE CLAIMS

The following is a listing of the claims pending in this application:

1-30. (Canceled)

31. (Previously Presented) A method for detecting von-Willebrand disease comprising the steps of:

- (a) detecting a binding activity of von-Willebrand factor (vWF) in a sample to a soluble form or a portion of glycoprotein 1b(α) (GP1b(α)) that is not associated with a platelet in the presence of ristocetin or a functionally equivalent substance;
- (b) determining an amount of vWF-antigen in said sample;
- (c) determining a ratio between the binding activity detected under step (a) and the amount of vWF-antigen determined under step (b) for said sample;
- (d) comparing the ratio obtained under (c) to a reference range; and
- (e) detecting von-Willebrand disease based on the comparison result obtained under step (d).

32. (Previously Presented) The method of claim 31, wherein detecting the binding activity under step (a) comprises detecting formation of a complex comprising vWF and GP1b(α).

33. (Previously Presented) The method of claim 31, wherein said soluble form or the portion of GP1b(α) is bound to a solid support.

34. (Previously Presented) The method of claim 33, wherein said soluble form or the portion of GP1b(α) is bound to said solid support by an anti-GP1b(α) antibody.

35. (Previously Presented) The method of claim 32, wherein said complex is bound to a solid support.

36. (Previously Presented) The method of claim 35, wherein said complex is bound to a solid support by an anti-GP1b(α) antibody, by an anti-vWF antibody, by an anti-Factor VIII antibody or by collagen.

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37. (Previously Presented) The method of claim 31, wherein detecting the binding activity under step (a) comprises using an anti-vWF antibody, an anti-Factor VIII antibody, an anti-GPlb(α) antibody, a collagen or mixtures thereof.

38. (Previously Presented) The method of claim 31, wherein detecting the binding activity under step (a) comprises using a heterogeneous or homogeneous assay.

39. (Previously Presented) The method of claim 38, wherein detecting vWF activity under step (a) comprises using an heterogeneous assay selected from the group consisting of enzyme linked immuno sorbent assay (ELISA), a radioimmunoassay (RIA), an immuno radio metric assay (IRMA), a fluorescent immunoassay (FlA), a chemiluminescent immuno assay (CLIA) and an electro chemiluminescent immuno assay (ECL).

40. (Previously Presented) The method of claim 38, wherein detecting the binding activity under step (a) comprises using an homogeneous agglutination assay.

41. (Previously presented) The method of claim 31, wherein the sample is obtained from blood, serum or plasma of a patient.

42-45. (Canceled)

46. (Withdrawn) A kit for detecting von-Willebrand disease (vWD) comprising:

- (a) a soluble form or a portion of glycoprotein 1b (α) (GPlb(α));
- (b) a ristocetin, or a functional equivalent substance; and
- (c) a solid support

47. (Withdrawn) The kit of claim 46, wherein the said soluble form or the portion of GPlb(α) is a recombinant protein.

48. (Previously Presented) The method of claim 31, wherein detecting von-Willebrand disease under step (e) comprises discriminating between different types of von-Willebrand disease.

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49. (Previously Presented) The method of claim 48, wherein detecting von-Willebrand disease under step (e) comprises discriminating between von-Willebrand disease type 1 and type 2.

50. (Previously Presented) The method of claim 31, wherein the soluble form or the portion of GPIb α is a recombinant protein.

51. (Previously Presented) The method of claim 37, wherein said antibody is a monoclonal antibody, a polyclonal antibody, a synthetic antibody, or a fragment of an antibody.

52. (Previously Presented) The method of claim 37, wherein said antibody or said collagen is detectably labeled.

53. (Previously Presented) The method of claim 35, wherein said solid support is selected from a group consisting of plastic, glass, silicon, metal, polystyrene, polyvinyl chloride, polypropylene, polyethylene, polycarbonate, dextran, nylon, amylose, natural or modified cellulose, polyacrylamide, agarose, magnetide and any combinations thereof.

54. (Previously Presented) The method of claim 53, wherein said solid support comprises a latex bead.

55. (Previously Presented) The method of claim 40, wherein said agglutination is measured by electric field variation, magnetic field variation, turbidimetric variation or light scattering.

56. (Previously Presented) The method of claim 41, wherein the sample is diluted.

57. (Previously Presented) The method of claim 31, wherein detecting the binding activity under step (a) comprises detecting a formed complex comprising vWF and GPIb α .

58. (Previously Presented) The method of claim 57, wherein said complex is bond to a solid support.

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59. (Previously Presented) The method of claim 58, wherein said complex is bound to a solid support by an anti-GP1b(α) antibody, by an anti-vWF antibody, by an anti-Factor VIII antibody or by collagen.

60. (Previously Presented) The method of claim 31, wherein the soluble form or the portion of GP1b(α) comprises an N-terminal domain of GP1b(α).

61. (Previously Presented) The method of claim 31, wherein the soluble form or the portion of GP1b(α) comprises amino acid residues His1-Val289 of GP1b(α).

62. (Previously Presented) The method of claim 48, wherein detecting von-Willebrand disease under step (e) comprises discriminating between von-Willebrand disease type 2A and type 2B.